

IN THE UNITED STATES DISTRICT COURT
 WESTERN DISTRICT OF TEXAS **FILED**
 SAN ANTONIO DIVISION

STANBIO LABORATORY, L.P.,	§
A Texas Limited Partnership, and	§
Plaintiff and Counter-Defendant	§
v.	§
HEMOCUE, INC. and	§
HEMOCUE AB	§
Defendants and Counterclaimant	§
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EKF-DIAGNOSTIC SALES, GmbH,	§
a German Corporation,	§
Plaintiff and Counter-Defendant	§
v.	§
HEMOCUE, INC. and	§
HEMOCUE AB	§
Defendants and Counterclaimants	§

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 CLERK US DIST COURT
 WESTERN DISTRICT OF TEXAS
 Civil Action No. SA03CA1080(OG)

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**STANBIO'S ORIGINAL ANSWER TO
 HEMOCUE'S ORIGINAL COUNTERCLAIMS**

Stanbio Laboratory, L.P. ("Stanbio") Answers Defendant HemoCue's Original Counterclaims as follows:

(Paragraphs 1 – 15 of Defendant HemoCue's Original Answer to Original Complaint, and Original Counter-Claim do not require Stanbio's response as they comprise HemoCue's answers to Stanbio's Original Complaint).

PARTIES

16. HemoCue AB is a corporation organized under the laws of Sweden with its principal place of business at Box 12045E-262 23 Angelholm, Sweden, and is the owner of U.S. Patent No. 5,674,457 ("the '457 Patent").

ANSWER:

Stanbio admits HemoCue AB's organization and address. Stanbio does not have sufficient information to either admit or deny HemoCue AB's claimed ownership of the '457 patent and leaves HemoCue to its proof.

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17. HemoCue, Inc., an affiliate of HemoCue AB, is a corporation organized under the laws of California with its principal place of business at 40 Empire Drive, Lake Forest, California, 92630, and is the exclusive licensee of the '457 Patent within the United States.

ANSWER:

Stanbio admits HemoCue, Inc.'s relationship with HemoCue, its organization, and its address. Stanbio does not have sufficient information to either admit or deny HemoCue, Inc. is the exclusive licensee of the '457 patent within the United States and leaves HemoCue to its proof.

18. Upon information and belief, Stanbio Laboratory, L.P. ("Stanbio") is a limited partnership organized under the laws of the State of Texas, with its principal place of business at 1261 North Main Street, Boerne, Texas, 78006.

ANSWER:

Admitted.

19. Upon information and belief, EKF-diagnostic GmbH ("EKF") is a corporation organized under the laws of Germany with its principal place of business at Ebendorfer Chaussee 3, D - 39179, Barleben / Magdeburg.

ANSWER:

EKF's location is admitted. Stanbio does not have sufficient information to either admit or deny the organizational allegations of this averment and, therefore, and leaves HemoCue to its proof.

20. Upon information and belief, EKF-diagnostic Sales, GmbH ("EKFS") is a corporation organized under the laws of Germany with its principal place of business at Ebendorfer Chaussee 3, D - 39179, Barleben / Magdeburg.

ANSWER:

EKF's location is admitted. Stanbio does not have sufficient information to either admit or deny the organizational allegations of this averment and, therefore, and leaves HemoCue to its proof.

21. Upon information and belief, EKF-Diagnostic Manufacturing, GmbH ("EKFM") is a corporation organized under the laws of Germany with its principal place of business at Ebendorfer Chaussee 3, D - 39179, Barleben / Magdeburg.

ANSWER:

EKF's location is admitted. Stanbio does not have sufficient information to either admit or deny the organizational allegations of this averment and, therefore, and leaves HemoCue to its proof.

22. Upon information and belief, both EKFS and EKFM are wholly owned subsidiaries of EKF.

ANSWER:

Stanbio does not have sufficient information to either admit or deny the allegations of this averment and, therefore, and leaves HemoCue to its proof.

JURISDICTION AND VENUE

23. This is an action for patent infringement under 35 U.S.C. § 271 et seq., and an action for unfair competition under the Trademark Act of 1946, as amended, 15 U.S.C. § 1051 et seq. ("Lanham Act").

ANSWER:

Stanbio admits this action arises under the stated laws but denies any violation of said laws.

24. This Court has federal subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338, and 15 U.S.C. § 1121.

ANSWER:

Stanbio admits the alleged federal subject matter jurisdiction.

25. Upon information and belief, Stanbio is a resident of this District and is subject to personal jurisdiction of this Court for this patent infringement action. Stanbio has purposely sold or offered for sale its blood-sampling products from this District with the expectation they will be purchased and used by consumers in the State of Texas. Therefore, personal jurisdiction over Stanbio is conferred under Article 11 of the United States Constitution.

ANSWER:

Admitted.

26. The acts and transactions complained of herein were conceived, carried out, made effective, and had effect within the State of Texas and within this District, among other places. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 (b) and (c) and 1400.

ANSWER:

Admitted.

27. The '457 Patent, entitled "Capillary Microcuvette," issued on October 7, 1997, is the patent in suit.

ANSWER:

Admitted.

28. The '457 Patent covers a device called a microcuvette that is sold to take blood samples from patients for testing hemoglobin levels in blood. A patient's finger is pricked so that a small sample of blood may be drawn into the microcuvette. The microcuvette is then placed into a reader to measure the hemoglobin level in blood samples. The patented microcuvette is designed to prevent bubbles from forming in the measuring zone of the microcuvette that might result in an inaccurate reading.

ANSWER:

Stanbio admits that "a patient's finger is pricked so that a small sample of blood may be drawn into the microcuvette. The microcuvette is then placed into a reader to measure the hemoglobin level and blood samples." The remainder of the allegation of this averment is denied as what the '457 patent "covers" is only the subject matter encompassed within the very limited scope of the '457 patent's very narrow claims, assuming the claims are valid and enforceable, which Stanbio denies.

29. HemoCue AB is the assignee and the owner of all right, title and interest in and to the '457 Patent.

ANSWER:

Stanbio does not have sufficient information to either admit or deny the allegations of this averment and leaves HemoCue to its proof.

30. HemoCue AB has granted HemoCue, Inc., an exclusive license to make, use, sell, offer to sell and import into the United States products under the '457 Patent.

ANSWER:

Stanbio does not have sufficient information to either admit or deny the allegations of this averment and leaves HemoCue to its proof.

FACTS RELATED TO PATENT INFRINGEMENT

31. Stanbio has in the past offered for sale and sold, and is currently offering for sale and selling, the HemoPoint® H2 Hemoglobin Measurement System for measuring hemoglobin levels in blood samples.

ANSWER:

Admitted

32. The HemoPoint® H2 Hemoglobin Measurement System utilizes microcuvettes called the H2 Microcuvettes.

ANSWER:

Admitted.

33. Upon information and belief, Stanbio entered into a distribution agreement with EKF to import and sell the H2 Microcuvettes in the United States. Under this agreement, EKFM manufactures the H2 Microcuvettes, and EKFS sells and delivers the H2 Microcuvettes to Stanbio for sale in the United States.

ANSWER:

Admitted.

34. Stanbio offers for sale and sells the H2 Microcuvettes under at least part numbers 3010-100 (sold in lots of 100 cuvettes), and 3010-200 (sold in lots of 200 cuvettes).

ANSWER:

Admitted.

35. Stanbio has imported into the United States, used, offered for sale and sold the H2 Microcuvettes, and such activities constitute infringement of the '457 Patent. Stanbio has induced others to use products that infringe the '457 Patent.

ANSWER:

Stanbio admits that Stanbio has imported into the United States, used, offered for sale, and sold the H2 microcuvettes. Stanbio denies that such activities constitute infringement of the '457 patent. Stanbio denies that Stanbio has induced others to use products that infringe the '457 patent upon the same basis.

FACTS RELATED TO UNFAIR COMPETITION

36. Stanbio prominently uses HemoCue's trade name and registered trademark HEMOCUE (the "HemoCue Mark") on package labels for the H2 Microcuvettes. For example, the product labels for HemoPoint® H2 Cuvettes prominently display the words "For Use with HemoPoint® H2 Meter and HemoCue® Meter." An example of Stanbio's product labeling is attached as Exhibit 1. This use of the HemoCue mark and trade name was done without HemoCue's consent.

ANSWER:

The Exhibit 1 referenced in this averment was not attached to the Complaint. Stanbio's packages are prominently labeled "HEMOPOINT® H2 Microcuvettes" on the top line in approximately 11 point type next to a large red Stanbio logo and the words "Stanbio Laboratory." The bottom of the label is comprised of red band which states in white relief, "Stanbio Laboratory.1261 North Main.Boerne, Tex. USA 78006."

Beneath the upper "HEMOPOINT® H2 Microcuvette" heading is the informative statement, "For use with the HEMOPOINT® H2 Meter and HEMOCUE® H-Hemoglobin Meter" in six-point type. This informative statement is a truthful statement and comprises a fair use of the term "HemoCue® H-Hemoglobin Meter." This is further explained at the bottom of the label: "HemoCue® is a registered trademark of HemoCue AG, Amgelholm, Sweden."

Nevertheless, because engaging in a long dispute over this minor matter is more trouble than it is worth, Stanbio is unilaterally taking steps so the above truthful informative reference to the H-Hemoglobin Meter will not be on future printing of the objected-to label.

Stanbio admits that Stanbio uses HemoCue's trade name and registered mark HemoCue in package labels for the H2 Microcuvettes and that the same is done without HemoCue's consent to the limited extent set forth above. The remainder of the allegations of this averment are denied for the reasons set forth above.

37. The use described above by Stanbio of the HemoCue Mark and trade name is likely to cause confusion, to cause mistake, and/or to deceive consumers and potential consumers of the parties, at least as to falsely implying (a) an affiliation, connection, or association of HemoCue with Stanbio, (b) an endorsement or sponsorship of the H2 Microcuvettes by

HemoCue, (c) an approval by HemoCue for the use of the H2 Microcuvettes with HemoCue's photometer, or (d) that HemoCue has granted a license to Defendants for the '457 Patent. On information and belief, other product literature improperly uses the HemoCue Mark and trade name.

ANSWER:

Denied.

38. Stanbio's improper use of the HemoCue Mark and trade name in the United States enables Stanbio to trade on and receive the benefit of goodwill HemoCue built up at great labor and expense over many years, and to gain acceptance of Stanbio's goods not solely on their own merit, but on the reputation and goodwill of HemoCue, the HemoCue Mark and trade name.

ANSWER:

Denied.

39. Stanbio's improper use of the HemoCue Mark and trade name in the United States unjustly enriches Stanbio at HemoCue's expense.

ANSWER:

Denied.

40. Stanbio's improper use of the HemoCue Mark and trade name in United States commerce has caused HemoCue to lose sales and has damaged their goodwill and reputation.

ANSWER:

Denied.

COUNT ONE

PATENT INFRINGEMENT UNDER 35 U.S.C. §271

41. HemoCue repeats the allegations above in paragraphs 31-40 as if fully set forth

ANSWER:

No response necessary. Stanbio repeats its statements set forth hereinabove..

42. Stanbio has imported into the United States, used, offered for sale and sold the H2 Microcuvettes, and such activities constitute infringement of the '457 Patent and active inducement of others to infringe the '457 Patent within the United States, all in violation of 35 U.S.C. § 271(a) and (b), all without the authorization of HemoCue.

ANSWER:

Stanbio admits it has imported into the United States, used, offered for sale, and sale the H2 Microcuvettes without the authorization of HemoCue. The remainder of the allegations of this averment are denied.

43. Upon information and belief, Stanbio had knowledge of the '457 Patent since at least prior to the time of committing acts of direct infringement and actively inducing others to infringe.

ANSWER:

Stanbio admits that it had knowledge of the '457 patent during the majority of the time it has imported into the United States, used, offered for sale, and sold the H2 Microcuvettes. Stanbio denies that it knew of the '457 patent prior to its first alleged act of infringement. Stanbio denies this averment's characterization of Stanbio's acts.

44. Upon information and belief, Stanbio's infringement of the '457 Patent has been willful.

ANSWER:

Denied

45. This case is an "exceptional" case within the meaning of 35 U.S.C. § 285.

ANSWER:

Denied

46. HemoCue has been irreparably harmed by Stanbio's acts of infringement of the '457 Patent and will continue to be harmed unless and until Stanbio's acts of infringement are enjoined and restrained by order of this Court. HemoCue has no adequate remedy at law and therefore seek both a preliminary and permanent injunction.

ANSWER:

Denied

47. As a result of Stanbio's acts of infringement and inducement of infringement of the '457 Patent, HemoCue has suffered and will continue to suffer damages in an amount to be proven at trial.

ANSWER:

Denied

48. Stanbio's infringing conduct has caused and will continue to cause irreparable injury to HemoCue unless preliminarily and permanently enjoined.

ANSWER:

Denied

COUNT TWO

UNFAIR COMPETITION UNDER LANHAM ACT, 15 U.S.C. §1125(A)

49. HemoCue repeats the allegations in paragraphs 31-40 above as if fully set forth herein.

ANSWER:

No answer is necessary. Stanbio repeats its answers set forth above.

50. The acts of Stanbio complained of herein constitute unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a).

ANSWER:

Denied

51. Stanbio's unauthorized use of the HemoCue Mark and trade name in the United States is likely to cause confusion, to cause mistake, and/or to mislead or deceive consumers and potential customers of the parties, at least as to falsely implying (a) an affiliation, connection, or association or HemoCue with Stanbio, (b) an endorsement or sponsorship of the H2 Microcuvettes by HemoCue, (c) an approval by HemoCue for the use of the H2 Microcuvettes with HemoCue's photometer, or (d) that HemoCue has granted a license to Stanbio for the '457 patent, and therefore constitutes unfair and fraudulent business practices in violation of 15 U.S.C. §1125(a).

ANSWER:

Denied

52. Unless the acts of Stanbio are restrained by this Court, Stanbio will continue to cause irreparable injury to HemoCue and to the public for which there is no adequate remedy at law.

ANSWER:

Denied

STANBIO'S AFFIRMATIVE DEFENSES

Stanbio asserts the following affirmative defenses to HemoCue's counter-claims.

53. None of Stanbio's activities or products have infringed any valid and enforceable claim of the '457 patent. Nor has Stanbio contributed to the infringement of any valid or enforceable claim of the '457 patent. Nor has Stanbio induced others to make, sell, offer for sale or import any products infringing any valid or enforceable claim of the '457 patent.

54. Upon information and belief, the '457 patent is invalid and/or unenforceable for failure to comply with the requirements, conditions, and provisions set forth in 35 U.S.C. §§ 101, 102, 103 and/or 112.

55. Upon information and belief, the '457 patent is unenforceable due to HemoCue's misconduct before the Patent Office, including its failure to disclose material and known prior art as required by, among other requirements, 37 C.F.R. § 1.56. By way of example only, HemoCue did not disclose to the Patent Office relevant facts concerning HemoCue's own commercially sold cuvettes although this information was material under 37 C.F.R. § 1.56.

55. Plaintiff's claim for patent infringement is limited or barred by the equitable doctrines of laches, estoppel, waiver, and acquiescence. HemoCue, in its several pleadings filed in this suit, affirmatively avoided objecting to Stanbio's sales of the subject cuvettes or stating that Stanbio's cuvettes infringed the '457 patent and consistently denied that it objected to Stanbio's cuvettes. Further, Stanbio provided HemoCue with samples of the Stanbio cuvettes in 2003 and requested HemoCue in writing to advise Stanbio if HemoCue believed the Stanbio cuvettes infringed HemoCue's '457 patent. HemoCue failed to respond to Stanbio's direct request for advice concerning whether HemoCue believed Stanbio infringed. HemoCue's pleadings and affidavits filed in the federal Western District of Texas action continually denied that HemoCue intended to file a suit against Stanbio in San Diego federal court alleging that Stanbio infringed the '457 patent.

56. On information and belief, all or part of Plaintiff's claims are barred by Plaintiff's unclean hands, patent misuse, and violation of the antitrust laws of the United States. In particular, Plaintiff failed to disclose material information concerning relevant prior art to the Patent Office. Additionally, even though HemoCue had information that cast substantial doubt upon the '457 patent's invalidity and the alleged infringement, HemoCue filed the instant suit attempting to enforce the '457 patent.

57. Plaintiff's unfair competition claims are barred by the defenses of fair use, nominal use and lack of actionable confusion. Stanbio's complained-of use of HEMOCUE on Stanbio's label within the term "For use with HemoPoint® H2 Meter and HemoCue®" is the minimal use necessary to truthfully inform customers and prospective customers that Stanbio's HemoPoint H2® cuvette fits within both Stanbio's HemoPoint® Meter and HemoCue's HemoCue® Meter. The packaging and advertising for Stanbio's cuvettes are prominently marked with Stanbio's own trademarks. The subject cuvettes are only sold in bulk quantities. Customers and prospective customers for bulk quantities of cuvettes are sophisticated purchasers. No customer or prospective customer of bulk quantities of Stanbio or HemoCue cuvettes has ever purchased or will ever purchase a Stanbio cuvette in the mistaken belief that it is purchasing a HemoCue cuvette due to the complained-of Stanbio label. If, *arguendo*, instances of confusion occurred, they are *de minimis*. HemoCue's assertion of this frivolous claim is barred by applicable trademark and antitrust law.

58. On information and belief, HemoCue has failed to act reasonably to mitigate the damages alleged in the complete

59. Stanbio reserves the right to amend and supplement its responses and affirmative defenses after further discovery.

PRAYER FOR RELIEF

WHEREFORE, Stanbio requests the following relief.

That HemoCue's counter-claims be dismissed with prejudice.

JURY DEMAND

Stanbio respectfully requests a trial by jury.

Respectfully submitted,

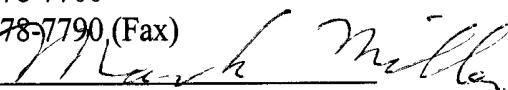
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CERTIFICATE OF MAILING

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